

Claim Amendments

1-8. (Canceled)

11 9. (Withdrawn) A pharmaceutical composition ~~[[.]]~~ comprising ~~[[a]]~~ the mono-PEG-IL-10 ~~[[of]]~~ according to claim ~~[[1]]~~ 21 in combination with a pharmaceutically acceptable carrier.

AI 12 10. (Withdrawn) A method of treating inflammation in an individual in need of such treatment, comprising administering to the individual a therapeutically effective amount of ~~[[a]]~~ the pharmaceutical composition ~~[[of]]~~ according to claim ~~9.~~ 11

13 11. (Withdrawn) A process for preparing ~~[[a]]~~ the mono-PEG-IL-10 according to claim 21, comprising the step of:

reacting IL-10 with an activated PEG-aldehyde linker in the presence of a reducing agent to form the mono-PEG-IL-10 ~~[[.]]~~ under conditions in which ~~wherein~~ the linker is covalently attached to one amino acid residue of the IL-10.

14 12. (Withdrawn) The process ~~[[of]]~~ according to claim ~~11~~ 12 wherein:  
(a) the reducing agent is sodium cyanoborohydride;  
(b) the activated PEG-aldehyde linker is PEG-propionaldehyde;  
(c) the PEG is a methoxy-PEG;  
(d) the linker is multi-armed;  
(e) the ratio of IL-10 to the sodium cyanoborohydride is from about 1:0.5 to 1:50;  
(f) the total molecular mass of all PEG comprising the PEG-aldehyde linker is from 3,000 daltons to 60,000 daltons; or  
(g) the reacting step is performed at a pH of 5.5 to 7.8.

15 13. (Withdrawn) The process ~~[[of]]~~ according to claim ~~11~~ 13, wherein the ratio of IL-10 to the sodium cyanoborohydride is 1:5 to 1:15.

16 14. (Withdrawn) The process ~~[[of]]~~ according to claim 11, wherein the total molecular mass of all PEG comprising the PEG-aldehyde linker is from 10,000 daltons to 36,000 daltons.

17 15. (Withdrawn) The process ~~[[of]]~~ according to claim 11, wherein the reacting step is performed at a pH of 6.3 to 7.5.

18 16. (Withdrawn) The process ~~[[of]]~~ according to claim 11, further comprising a step selected from:

incubating the mono-PEG-IL-10 product in a buffer at pH 5.0 to 9.0;

~~[[and]]~~ or

treating the mono-PEG-IL-10 product with 0.05 to 0.4 M hydroxylamine HCl salt.

17-20. (Canceled)

21. (New) A mono-pegylated Interleukin-10 (mono-PEG-IL-10) comprising one or more polyethylene glycol (PEG) molecules covalently attached via a linker to a single amino acid residue of IL-10, wherein said amino acid residue is the alpha amino group of the N-terminal amino acid residue or the epsilon amino group of a lysine residue.

22. (New) The mono-PEG-IL-10 of claim 21, wherein one or two PEG molecules are attached to said single amino acid residue.

23. (New) The mono-PEG-IL-10 of claim 21, wherein one subunit of said IL-10 has the formula:

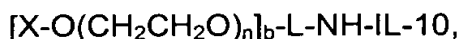


wherein b is 1-9 and L is a C<sub>2-12</sub> alkyl linker moiety covalently attached to a nitrogen (N) of said single amino acid residue.

3  
4 24. (New) The mono-PEG-IL-10 of claim 23, wherein b is 1 and L is -CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>-.

25. (New) The mono-PEG-IL-10 of claim 21, wherein PEG is covalently attached to the nitrogen of the alpha amino group of the N-terminal amino acid residue.

6 26. (New) The mono-PEG-IL-10 of claim 21, wherein said IL-10 has the formula:



wherein X is H or C<sub>1-4</sub> alkyl, n is 20 to 2300, b is 1 to 9 and L is a C<sub>1-11</sub> alkyl linker moiety which is covalently attached to the nitrogen (N) of the alpha-amino group at the amino terminus of one IL-10 subunit; provided that when b is greater than 1, the total of n does not exceed 2300.

7 27. (New) The mono-PEG-IL-10 of claim 26, wherein L is -CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>-.

8 28. (New) The mono-PEG-IL-10 according to claim 21, wherein said mono-PEG-IL-10 has greater than 30% of the activity of unconjugated IL-10.

9 29. (New) A composition of pegylated IL-10 comprising the mono-PEG-IL-10 according to claim 21, wherein the population of mono-PEG-IL-10 is at least 80% of a positional isomer in which the PEG is conjugated to the N-terminal amino acid of one subunit of IL-10.

10 30. (New) A process for preparing a pharmaceutical composition comprising the mono-PEG-IL-10 according to claim 21, comprising mixing the mono-PEG-IL-10 with a pharmaceutically acceptable carrier.